



## Investor News

**Not intended for U.S. Media**

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### **U.S. FDA Approves Bayer's Gadobutrol Injection for MRI of the Central Nervous System**

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**Leverkusen, March 15, 2011** – Bayer HealthCare Pharmaceuticals announced today that the U.S. Food and Drug Administration has approved Bayer's gadobutrol injection Gadavist™ (gadobutrol), a 1.0 molar macrocyclic gadolinium-based contrast agent (GBCA) for intravenous use in diagnostic magnetic resonance imaging (MRI) in adults and children age two and older to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system (CNS). Gadavist™ is known as Gadovist® outside the U.S. and is approved in over 60 countries.

"We are very happy to offer gadobutrol injection to U.S. healthcare providers, an important new option for contrast-enhanced MRI of the CNS," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. Our MR contrast agents are some of the most widely used today, and Bayer is proud to be a world leader in diagnostic imaging."

MRI has been used by physicians for more than 25 years to create detailed images of the human anatomy. Contrast agents are often used to better visualize anatomic structures and pathologies.

#### **About the U.S. Clinical Phase III trials**

Data submitted by Bayer for approval included results from two Phase III studies that confirmed the efficacy and safety of 1.0 molar gadobutrol injection in contrast enhanced MRI of the CNS. The first Phase III study compared the efficacy of combined gadobutrol-enhanced images plus unenhanced (without injection of contrast agent) images to unenhanced images alone. The second Phase III study used a crossover design with an active control, gadoteridol, to also compare the efficacy of the combined gadobutrol-enhanced plus unenhanced images to unenhanced images alone, as well as to confirm noninferiority of combined gadobutrol imaging versus combined gadoteridol imaging.

To learn more about imaging techniques, please visit:

[www.bayerscheringpharma.de/imaging\\_techniques](http://www.bayerscheringpharma.de/imaging_techniques)

[www.diagnostic-imaging.bayerscheringpharma.de](http://www.diagnostic-imaging.bayerscheringpharma.de)

### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 16.913 billion (2010), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55.700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

Find more information at [www.bayerhealthcarepharmaceuticals.com](http://www.bayerhealthcarepharmaceuticals.com).

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### **Forward-Looking Statements**

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